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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,052

07/13/2006

Katsumi Mochitate

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09/18/2008

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,052	MOCHITATE, KATSUMI	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/23/05;4/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and 28 drawn to a hydrophobic cell culture substrate.

Group II, claim(s) 16-25, drawn to an immobilized preparation having a cell adhesive protein or peptide.

Group III, claim(s) 26 and 27, drawn to a method for preparing an immobilized preparation having a functional group capable of reacting with a protein or peptide.

Group IV, claim(s) 29-34, drawn to artificial tissues.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: A cell culture substrate coated with a hydrophobic polymer, an immobilized preparation, a method of making said composition and artificial tissues thereof are disclosed by Banes et al. (US 4,789,601). Banes et al. teaches a polyorganosiloxane composition having a biocompatible surface thereon is disclosed. The biocompatible surface results from the derivatization, or amination, of the surface intended for cell contact. Banes does not specifically teach that polyorganosiloxanes are hydrophobic and linear. Johnson et al. (US 6,503,490) disclose that polyorganosiloxanes are inherently hydrophobic and are linear (col. 6, lines 50-55). The Johnson et al. reference is cited to point out that hydrophobicity and linear structures are an inherent properties of polyorganosiloxanes. The composition can be utilized for cell culture substrate or in a variety of artificial organ applications such as breast implants, synthetic blood vessels, joints, tendons and heart valves (abstract). Examples 1-5 disclose the method of making the biocompatible surface. Thus, Banes et al. teach at least claims 1, 16, 26 and 29. Because the claims fail to make a contribution over the prior art, it is clear that all claims as filed fail to

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provide special technical feature common to all claimed inventions. Because the claims as filed lack a common special technical feature, the claims lack unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is required to elect species relevant to the elected Group *supra*.

The species are as follows:

A. Elect one cell culture substrate from those listed in claims 2 or 10-12.

Based on an election of claim 2, if a bio-based polymer is chosen, further elect the type from those listed in claim 3. If a plastic is elected, further elect a thermoplastic resin or a thermosetting resin. If a thermoplastic resin is elected, select one from those listed in claim 5. If a thermosetting resin is elected, select one from those listed in claim 6. If an inorganic material is elected, select one from claim 8. If a metal is elected, select one from claim 9.

For a selection from claims 10-12, select if the substrate is a well (includes claim 12), a printed wiring board or an artificial organ (if an artificial organ is selected. Elect one from claim 11.

B. For the hydrophobic binding-absorptive polymer I, elect a value for R^1 , X and Z.

C. Elect the peptide region relates to fibronectin (claims 21 and 22) or laminin. If laminin is elected, select one TG-domain peptide from those listed in claim 24. Applicant

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is reminded that sequences must have a corresponding SEQ ID No. unless the peptide is in the public domain.

D. Applicant is required to elect a cell for an artificial tissue from an epithelial cell, endothelial cell, a mesenchymal cell or an artificial tissue. Upon the election of one of these cell types, Applicant is further required to select the type of epithelial cell (claim 31), endothelial cell (claim 32), a mesenchymal cell (claim 33) or an artificial tissue (claim 34).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

For specie A, the corresponding claims are 1-12.

The following claim(s) are generic: claim 1 and 28.

For specie B, the corresponding claims are 13-15.

The following claim(s) are generic: claim 1 and 28.

For specie C, the corresponding claims are 25-27.

The following claim(s) are generic: claim 16-20.

For specie D, the corresponding claims are 30-34.

The following claim(s) are generic: claim 29.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

For specie A, the various substrates are composed of distinct materials having different binding abilities and chemical reactivity.

For specie B, the selection of different values (e.g., atoms or functional groups) determine to reactivity and properties of the polymer.

For specie C. The claimed peptides have distinct binding specificities.

For Group D, the artificial tissues have distinct biological functions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Susan Hanley/
Examiner, Art Unit 1651